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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,912	05/16/2006	Federico Mailland	622-91	5633

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,912	MAILLAND, FEDERICO	
	Examiner	Art Unit	
	JENNIFER M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/09;1/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed June 12, 2009 have been received and entered into the application. Upon further consideration, the species election made in the previous Office Action is withdrawn. Accordingly, claims 18-33 have been examined.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treatment of vaginal fungal infections", does not reasonably provide enablement for the "**prevention** of vaginal fungal infections". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors**

have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method for the prevention and treatment of vaginal fungal infections which comprises the administration of a formulation comprising ascorbic acid or a physiologically acceptable salt thereof to a patient in need of such a treatment wherein said formulation is administered after completion of the standard treatment against bacterial, fungal or protozoarian infections. The nature of the invention is extremely complex in that it encompasses the actual **prevention** of fungal infections (i.e. mycoses) such that the subject treated with above compounds does not contract fungal infections.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass **prevention** of fungal infections in humans which has potentially many different causes (i.e. many different group of fungi). Each of which may or may not be addressed by the administration of the claimed compound.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually **prevent** the actual development of fungal infections is minimal. All of the guidance provided by the specification is directed towards **treatment rather than prevention** of fungal infections.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of fungal infections.

State of the Art: While the state of the art is relatively high with regard to treatment of fungal infections (i.e. yeast infection), the state of the art with regard to **prevention** of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to **prevent** development of fungal infections.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of fungal infections in a human subject with the claimed compounds makes practicing the claimed invention unpredictable in terms of **prevention** of fungal infections.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **prevention** of fungal infections. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard **prevention** of fungal infections with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage,

duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding prevention of fungal infections with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of fungal infections in a subject by administration of one of the claimed compounds.

Therefore, a method for the prevention and treatment of vaginal fungal infections which comprises the administration of a formulation comprising ascorbic acid or a physiologically acceptable salt thereof to a patient in need of such a treatment wherein said formulation is administered after completion of the standard treatment against bacterial, fungal or protozoarian infections is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng (U.S.Patent No. 6,770,306 B1) in view of Hotzel et al. (U.S.Patent No. 5,371,107).

Zeng teaches that fungal vaginitis can be treated with a pharmaceutical composition for reducing vaginal acidity. Zeng teaches that abnormal enhancement of vaginal acidity causes damage to vaginal mucous membrane and results in vaginitis. (abstract, column 1, lines 5-10, column 2).

Zeng does not teach the administration of ascorbic acid, the specified fungal infections set forth in claims 24-27 and the administration to patient after completion of antimicrobial agents set forth in claims 20 and 21.

Hotzel et al. teach that a medicinal composition in the form of an ointment or tablet containing about 3% to about 50% by weight of ascorbic acid. (abstract). Hotzel et al. teach that the local use of vitamin C eliminates the potential pathogenic bacteria by acidification. (column 2, lines 63-67).

It would have been obvious to one of ordinary skill in the art to employ Hotzel et al's vitamin C (ascorbic acid) composition for the treatment of vaginal fungal infections such as fungal vaginitis. One would have been motivated to make such a modification

in order to achieve reduction of vaginal acidity in the patient's suffering form fungal vaginitis disclosed by Zeng et al. by administration of Hotzel's medicinal composition containing ascorbic acid which is known to acidify the vagina. There is a reasonable expectation of successfully treating vaginal fungal infections with vitamin C (ascorbic acid) composition of Hotzel et al. because vitamin C acidifies, therefore, it reduces acidification of vaginal mucous membrane that is necessary to eliminate vaginal fungal infection as taught by Zeng et al. With regard to the initiation of ascorbic acid after the completion of the specified antibiotics set forth in claims 20 and 21, such is obvious because it is well known in the art that after a completion of an antibiotic treatment, there is increased chance of the patient having a fungal infection due to the antibiotic treatment destroying a normal flora. With regard to the cause of the fungal infections set forth in the claims 24-27 such is obvious because Hotzel e al. teach that the reduction of vaginal acidity is useful in treating vaginal fungal infection in general. Therefore, the employment of ascorbic acid by reducing vaginal acidity would treat a fungal infection in general regardless of the specific causes. For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk

August 31, 2009